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EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

NOTIFICATION DATE	DELIVERY MODE
08/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/540,392	MARKUS, BEIER	
	Examiner	Art Unit	
	TERESA WESSENDORF	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-38* is/are pending in the application.

4a) Of the above claim(s) *20 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,19 and 22-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/10/08 has been entered.

Status of Claims

Claims 18-38 are pending

Claims 20 and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species.

Claims 18-19 and 22-38 are under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-19, 24-25, 27-28, 30-34 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Schuetz et al (Journal of Analytical Chemistry (1999), 363(7), 625-631).

Schuetz et al discloses throughout the article at e.g., the abstract:

> A multianalyte immunosensor array can he implemented by immobilization of different haptens in distinct areas of a single cavity or flow cell. In this case a mixture of different antibodies for different analytes is used in an indirect ELISA-format. The selection of the right hapten structures is very important to build up an array successfully. A system of independent hapten/antibody combinations is needed, with one immobilized hapten (coating antigen) reacting only with one antibody. If more than one antibody binds to a coating antigen no ideal calibration curves are obtained. This phenomenon is known as shared-reactivity and can lead to double-sigmoidal curves. To use monoclonal antibodies to 2,4,6 trinitrotoluene (TNT) and 2,4-dichlorophenoxyacetic acid (2,4-D), two different haptens had to be found, one only reacting with the TNT-antibody, the other only binding to the 2,4-D-antibody. 2,4-Dichlorophenoxybutyric acid was used for the 2,4-D antibody and 2,4,6-trinitrophenyl-8-aminooctanoic acid for the TNT antibody. Although 4-nitrotoluene, 2,4-dinitrotoluene and 4-amino-2,6-dinitro-toluene showed only very low cross reactivities to the 2,4-D antibody, the corresponding haptens 4-nitrophenyl-acetic acid, 2,4- dinitrophenyl-6-aminohexanonic acid, and 4-amino-2,6-dinitrotoluyl- (N)-glutarate are useful coating antigen for this antibody….. It could he shown that the affinity consts. of an antibody to the analytes are the main sensitivity and selectivity determining parameters for competitive immunoassays. A two-dimensional microtiter plate array was used to determine the analytes 2,4-D and TNT in parallel with a mixture of antibodies.

See further the specifics of the method at e.g., page 626 under the Materials and methods section.

Accordingly, the method of Schuetz which uses specific process steps using the specific haptens and polymeric receptors fully meet the broad claimed method utilizing broad components therein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18-19 and 22-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Stahler et al (WO 0013018)(I) or (WO 0289971)(II) or (WO 02/32567)(III) in view of anyone of Wu et al (7034134) or Gray et al (6555310) or Edwards (6455280).

Stahler et al (I) discloses throughout the entire document at e.g., page 2 and the claims a method for producing a carrier for the determination of analytes, comprising: (a) providing a microfluidic carrier, (b) passing liquid with receptor building

blocks for synthesizing polymeric receptors over predetermined zones on the carrier, (c) immobilizing the receptor building blocks in said predetermined zones on the carrier and (d) repeating steps (b) and (c) until the desired receptors have been synthesized in the predetermined zones using the receptor building blocks, wherein hapten groups are applied to the carrier before, during or/and after the synthesis of the receptors. (U.S. No.7, 097,974 is the national stage entry of WO 0013018, as stated in the Remarks submitted on 6/10/2008.)

See the abstract of each of the Stahler (II) and (III) references. (Please note applicants' remarks made on 6/10/2008, with regards to the corresponding US applications of these two WO Patents).

None of the Stahler references teaches a hapten attached to the carrier. However, Wu discloses throughout the patent at e.g., col. 127, lines 23-27:

> **Protein** fusions involving polypeptides of the present invention, including fragments and/or variants thereof, can be used for the following…….determination of **protein-protein** interactions via immunoprecipitation, purification of **proteins** via affinity chromatography, functional and/or structural characterization of **protein**……. also encompasses the application of hapten specific antibodies for any of the uses referenced above for epitope fusion **proteins**. For example, the polypeptides…. could be chemically derivatized to **attach** hapten molecules (e.g., **DNP**,…_. Due to the availability of monoclonal antibodies specific to such

haptens, the **protein** could be readily purified using immunoprecipation, for example.

Gray et al discloses throughout the patent at e.g., col.

13, line 10 up to col. 14, line 56:

Selection of polyvalent library members is performed by contacting the library with the receptor for the tag component of library members. Usually, the library is contacted with the receptor immobilized to a **solid phase** and binding of library members through their tag to the receptor is allowed to reach equilibrium. The complexed receptor and library members are then brought out of solution by addition of a **solid phase** to which the receptor bears affinity (e.g., an avidin-labelled **solid phase** can be used to **immobilize biotin**-labelled receptors). Alternatively, the library can be contacted with receptor in solution and the receptor subsequently immobilized. The concentration of receptor should usually be at or above the Kd of the tag/receptor during solution phase binding so that most displayed tags bind to a receptor at equilibrium. When the receptor-library members are contacted with the **solid phase** only the library members linked to receptor through at least two displayed tags remain bound to the **solid phase** following separation of the **solid phase** from library members in solution. Library members linked to receptor through a single tag are presumably sheared from the **solid phase** during separation and washing of the **solid phase**. After removal of unbound library members, bound library members can be dissociated from the receptor and **solid phase** by a change in ionic strength or pH, or addition of a substance that competes with the tag for binding to the receptor. For example, binding of metal chelate ligands immobilized on agarose and containing Ni.sup.2+ to a hexahistidine sequence is easily reversed by adding imidazole to the solution to compete for binding of the metal chelate ligand. Antibody-**peptide** binding can often be dissociated by raising the pH to 10.5 or higher.

Edwards discloses throughout the patent at e.g., col. 79,

line 59 up to col. 80, line 40:

Microsequencing may be achieved by the established microsequencing method or by developments or derivatives thereof. Alternative methods include several **solid-phase** microsequencing techniques. The basic microsequencing protocol...[method] is conducted as a heterogeneous phase assay, in which the primer or the target molecule is immobilized or captured onto a solid **support**. To simplify the primer separation and the terminal nucleotide addition analysis, oligonucleotides are attached to solid **supports** or are modified in such ways that permit affinity separation as well as polymerase extension. The 5' ends and internal nucleotides of synthetic oligonucleotides can be modified in a number of different ways to permit different affinity separation approaches, e.g., biotinylation. If a single affinity group is used on the oligonucleotides, the oligonucleotides can be separated from the incorporated terminator regent. This eliminates the need of physical or size separation. More than one oligonucleotide can be separated from the terminator reagent and analyzed simultaneously if more than one affinity group is used. This permits the analysis of several **nucleic** acid species or more **nucleic** acid sequence information per extension reaction. The affinity group need not be on the priming oligonucleotide but could alternatively be present on the template. For example, immobilization can be carried out via an interaction between biotinylated DNA and streptavidin**-coated** microtitration wells or avidin**-coated** polystyrene particles. In the same manner, oligonucleotides or templates may be attached to a solid **support** in a high-density format….Other possible reporter-detection pairs include: ddNTP linked to **dinitrophenyl (DNP**) and anti**-DNP** alkaline phosphatase conjugate.. or biotinylated ddNTP and horseradish peroxidase-conjugated streptavidin with o-phenylenediamine as a **substrate** …….

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use hapten such as biotin or dinitrophenol in the method of anyone of Stahler et al as taught by Wu or Edwards or Gray. Each of Wu, Edwards and Gray teaches the

conventionality of using various haptens that binds to different receptors such as nucleic acid or protein. One would have a reasonable expectation of success in using said hapten as successfully achieved by Edwards or Wu or Gray in purifying various compounds.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0765. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/TERESA WESSENDORF/

Primary Examiner, Art Unit 1639